Reviewer’s report

Title: Novel affordable medical devices: case studies of innovative companies from India

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Reviewer: Warren Kaplan

Reviewer’s report:

In brief, I think this paper needs major compulsory revisions before I would publish it. It has the potential to be a really novel study, but I am not sure that it can be re-worked sufficiently to reach this result, in my opinion.

Is the question posed original, important and well defined?

The research question posed by the authors is, in my view, not very well identifiable.

1. In the abstract, last sentence, it is stated “We have sought to understand what enablers and barriers they [the companies] encountered.” To what end is this understanding sought? How will this information be used?

Notwithstanding, this is an original piece of work to the extent that such case study-type investigations have really only been done with respect to pharmaceutical producers and not for makers of medical devices. However, the paper would take on added value and importance if additional information is included.

2. Further, I struggled with finding a clear conclusion to this study. As written, and I am guilty of this as well, the conclusions look like a list of barriers and enablers, none of which seems unique to the medical device industry. There is also a 'wish list' of recommended policies (e.g., strengthen capacity and interdisciplinary work culture of the national device regulatory body, institutionalize health care payers and medical councils and associations). I would be more impressed, and I think it would add tremendous value, if authors could do at least a rudimentary stakeholder analysis (See for instance, http://www.who.int/workforcealliance/knowledge/toolkit/33.pdf) to provide an in depth analysis of stakeholders/agendas/ strengths/weaknesses.

Are the data sound and well controlled? Are the methods appropriate?

I am not really qualified to comment on details of qualitative case study methods.

3. However, I note that the references cited as “used by others to study medical innovation in developing countries [8, 14-16] …” (Methodology section, first sentence) were all developed for pharmaceuticals. This raises for me the basic question of whether or not the different business models of a medical device vs. a pharmaceutical should be discussed somewhere in the paper. Indeed, these
different business models may be a major driver of the results of this study. The biggest difference is the extremely rapid medical device product development cycle (certainly as compared to pharmaceuticals). Do the authors think this has an impact?

4. In the Methodology section, first paragraph, the authors initially did 40 interviews and then selected six companies based on several sources (BioSpectrum India Life Sciences Resource Guide 2010 etc.) but that begs the question as to what criteria were used, i.e., the largest sales by volume? Value? highest ROI? Highest profit? lowest debt ratio? This should be made clearer.

Regarding the methodology section, final sentence, I wonder if the authors used any type of software such as NVivo® (http://www.qsrinternational.com/products_nvivo.aspx ) to “code” responses or develop various domains of knowledge or understanding. Essentially, I am asking if there was any analytical process to parse out and classify the material from the interviews?

Is the interpretation (discussion and conclusion) well balanced and supported by the data?

Generally, I think they are well balanced and overall are based directly from the data. I have several questions/issues in this regard as follows:

First paragraph of Conclusion: “Although FDA, CE and WHO certifications are an alternative, the high cost of such procedures…” Please provide evidence and a reference for this assertion.

Last sentence of Conclusion: “Because of the complexity of such settings, accessing the market requires ground-breaking strategies also in the post-R&D phases of the product lifecycle.”

I do not understand this sentence. Have I missed a discussion of these "ground breaking" strategies already in the text? What does “ground breaking” mean in this sentence? In my view, this document has many of these unclear terms, summarized in more detail below.

Can the writing, organization, tables and figures be improved?

I have some specific comments about this, listed below.

I notice there is no “Results” section as labeled. The ‘results’ appear to start with the section called “The companies and their products”.

Third paragraph of “Background”: perhaps the authors could define “health technology assessment”

Fourth paragraph of “Background”: “In contrast, India doesn’t have a formalized national HTA process, the public health system is generally underdeveloped and not very open to new technologies…” Possibly correct, although arguable, but what is the evidence for this sweeping statement?

5. Section called “Companies and their products”, second paragraph.
The discussion about “… an independent assessment of the needs of health-care providers” may well be the most interesting and original part of this paper. It could be very informative and original. How these companies ascertain "unmet medical need" with regard to devices? Much of this information is behind closed doors. Any insight into this so-called "market- and consumer- research" from a public health viewpoint is most interesting. What kind of “market” is there if most people pay out of pocket? Some more insight into what GEH did in their surveys would also be relevant. Supplemental Table 3, in my view, is very interesting and somehow should be incorporated more in the text.

What about issues of intellectual property relevant to these companies? I assume there is no information here on the IP policies? Is India the only country where patents were filed? Almost NOTHING known about this subject for medical devices (as opposed to medicines).

6. In my view, Table 1 already contains more information but it could be re-formatted which will force the text to be more focused. Have more columns than just the products, e.g., product/sources/IP issues/collaborators.

The last sentence of the section called “Experience with international…” talks about “high uncertainty related to the Indian public market”. I assume this is the ‘uncertainty” mentioned in the next section? If not, then this should be clarified somehow.

7. In the “Policy implications” section, the authors should think about discussing this ‘wish list’ a bit more (see comment above about a stakeholder analysis).

“…The process should be made more transparent through the incorporation of explicit evidence based decision making…”

Such as? Any models in other countries? NICE in the UK? Is this likely to happen in India?

“novel regulatory mechanisms…”

That begs the question, do the authors have any ideas about this? Do the authors have suggestions? Are other countries thinking about this?

In short, I would recommend revisions for all of the following reasons: data need to be added to support the authors’ conclusions; better justification is needed for the arguments based on existing data; or the clarity and/or coherence of the paper needs to be improved.

I am not aware of any ethical/conflict issues that have not been adequately addressed.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests'